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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,244	05/16/2001	Narendra Bhadra	M41.1	8097

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,244

Applicant(s)

BHADRA ET AL.

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/13/06 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22, 23 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanagho et al (EP 0245547). Tanagho discloses the claimed invention of simultaneous pulses as seen on page 9, line 45, that the pulses may "overlap" and in claim 6, the pulses can be

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simultaneous. In addition, although Tanagho does not provide a step of placing the electrode on a dorsal root, he is capable of meeting the functional use recitations presented in the claim of having the electrode on the dorsal root (claims 22 and 23) and inherently transmits the pulses to the dorsal root (claim 22) since he provides at least two nerve electrodes that can be placed on the roots and since he states that the electrodes will stimulate the dorsal nerves (page 4, line 5). But, Tanagho does not disclose the use of surface mounted electrodes (claims 26 and 27) or the particulars of the stimulation pulse parameters, such as the quasitrapezoidal pulse trains at 20 Hz (claim 28), an intermittent pulse train on and off for 1 second each (claim 23), the second electrode pulse having a nominal amplitude of 1 ma and a pulse duration of 20-100 usec (claim 29), and the first electrode pulse having a nominal amplitude of 1 ma and pulse duration of 350-500 usecs (claim 30).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the nerve stimulation system and pulse parameters of the nerve cuff electrodes as taught by Tanagho, with the use of surface mounted electrodes or the particulars of the stimulation pulse parameters, such as the quasitrapezoidal pulse trains at 20 Hz (claim 28), an intermittent pulse train on and off for 1 second each (claims 22 and 23), the second electrode pulse having a nominal amplitude of 1 ma and a pulse duration of 20-100 usec (claim 29), and the first electrode pulse having a nominal amplitude of 1 ma and pulse duration of 350-500 usecs, since it was known in the art that: surface mounted electrodes are used to provide the stimulation pulses to the nerves to provide a non-invasive systems that does not require surgery; and cuff electrodes used to stimulate different nerves apply different and particular pulse parameters, such as the quasitrapezoidal pulse trains at 20 Hz (claim 28), an

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intermittent pulse train on and off for 1 second each (claims 22 and 23), the second electrode pulse having a nominal amplitude of 1 ma and a pulse duration of 20-100 usec (claim 29), and the first electrode pulse having a nominal amplitude of 1 ma and pulse duration of 350-500 usecs, so that the nerves can be effectively stimulated to activate or block particular diameter nerves and since it is known in the art that different electrode sizes and spacing require different signals to activate or block different nerves. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation system as taught by Tanagho with the particular pulse parameters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanagho et al in view of Fang et (5199430).

Tanagho discloses the claimed invention except for the use of self sizing cuff electrodes. Fang teaches that it is known to use self sizing cuff electrodes to allow the electrode to be secured to the nerve to prevent current leakage and allow easy installation of the electrodes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the nerve stimulation system as taught by Tanagho, with the self sizing cuff electrodes as taught by Fang, since such a modification would provide a nerve stimulation system with self sizing cuff electrodes to allow the electrode to be secured to the nerve to prevent current leakage and allow easy installation of the electrodes.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. It is suggested to change claim 22, to make it allowable, to something similar to

“simultaneously transmitting a second series of stimulus pulses comprising an intermittent pulse train pattern of 1 second on/1 second off to a sacral dorsal root corresponding to the sacral ventral root of the patient with a second electrode to stimulate the dorsal root;

wherein both series subdue urethral reflexes and enhance voiding to empty the bladder.”

This language was taken from page 4 of the specification and reads over the prior art or Tanagho or Fang since the prior art does not state that the dorsal root is stimulated to subdue reflexes and enhance voiding.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

4/8/6

GRE
April 8, 2006